IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	
Nordine CHEIKH *et al.*	Art Unit: 1631
Appln. No.: 09/976,054	Examiner: Mary K. ZEMAN
Filed: October 15, 2001	Atty. Docket: 16517.256
Title: **Nucleic Acid Molecules and Other Molecules Associated with the Cytokinin Pathway**	Confirmation No.: 3580

APPELLANT'S AMENDED BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Appeal Brief - Patents

Sir:

This is an Appeal from the Final Rejection of claims 1, 12 and 14-19 in the above-described patent application. A Notice of Appeal was filed on August 4, 2003. An Appellant's Brief was filed October 6, 2003, at which time the statutory fee of $320.00 for submitting an appeal brief was paid. This Amended Brief is submitted in response to the Office Communication mailed March 4, 2004 which alleged that the Brief filed August 28, 2003 was non-compliant with 37 C.F.R. 1.192(c). *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 12-19 are pending. Claims 1, 12, and 14-19 stand finally rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support. Claims 1 and 18-19 stand finally rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make an use the claimed invention.

Claim 13 stands objected to as being dependent on a rejected base claim. In the Final Office Action mailed May 5, 2003 the Examiner indicated that claim 13 "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims."

Appellant appeals all of the rejections of claims 1, 12 and 14-19.

4. Status of Amendments

Appellant has not filed any amendments in this case subsequent to the Final Office Action mailed May 5, 2003 ("Final Action").

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5. Specification at page 19, line 2 through page 20, line 7. The invention is further directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. *Id.* The invention is further directed to a substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 5 or complement thereof. Specification at page 19, line 2 through page 20, line 7; and page 37, line 16 through page 39, line 23. The present invention is further directed to a substantially purified first

nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof which specifically hybridizes to a second nucleic acid molecule, the second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. *Id.*

6. Issues

The issues in this Appeal are:

(a) whether claims 1, 12, and 14-19 are unpatentable under 35 U.S.C. § 112, first paragraph (and whether claim 13 is allowable without rewriting in independent form) for alleged insufficiency of written description; and

(b) whether claims 1 and 18-19 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement.

7. Grouping of Claims

Claims 1 and 12-19 remain in this case. Claims 1, 12, 14 and 18 are independent. All of the claims at issue do not stand or fall together and the separate patentability of claims 1, 12, 14-17 and 18-19 is particularly addressed in Sections 8.C(3), 8.C(4) and 8.C(5). A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Preliminary Remarks

Appellant notes that the Examiner has indicated that claim 13 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

B. Summary of Appellant's Position

Appellant has provided an adequate description of the claimed nucleic acids that demonstrates Appellant's possession of the claimed invention. Each genus of claimed

nucleic acid molecules, *i.e.*, the nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO: 5 and its complement, has been described by the recitation of a common structural feature – the nucleotide sequence of SEQ ID NO: 5 and its complement, respectively – which distinguishes molecules in the genus from molecules not in the claimed genus. Because the specification demonstrates that Appellant has possession of (and has provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Appellant has asserted that the claimed nucleic acid molecules actually work for the utilities disclosed and described in the specification, and so the enablement rejection must be reversed. Appellant has asserted that one skilled in the art is able to use the claimed nucleic acid molecules for at least two disclosed utilities, namely use to identify the presence or absence of a polymorphism and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 55, line 5, through page 82, line 16. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Appellant has asserted that the claimed nucleic acid molecules work for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

C. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that SEQ ID NO: 5 is adequately described by the specification,[1] the adequacy of the written description of claims 1, 12, and 14-19 has been challenged by the Examiner because the subject matter of the claims is allegedly

[1] The Examiner has previously stated that "[c]laims limited to isolated polynucleotides consisting of the SEQ ID NO: 5 would meet the written description provisions of 35 USC § 112, first paragraph." Office Action mailed December 19, 2002, at page 3.

"not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 2. The Examiner contends that "[t]here is no description of an isolated maize or soybean polynucleotide which is a full length polynucleotide comprising an open reading frame which would encode a full length enzyme...[t]herefore, this genus lacks written description." Final Action at pages 2-3. The Examiner further alleges that "[a]pplicant is *not* in possession of any polynucleotide which encodes a maize or soybean APRT enzyme. Therefore, the disclosure is deficient, and the claims lack adequate written description."[2] Final Action at page 3. These assertions do not form a proper basis for a written description rejection of a "comprising" claim. If they did, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Moreover, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d

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[2] Appellant notes that the Examiner's arguments regarding adequacy of § 112 description fail to specifically address the subject matter of claims 12 and 14-17, which are drawn to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. Nevertheless, Appellant intends the arguments herein to be fully responsive to alleged rejections of claims 1, 12, and 14-19. Moreover, the Examiner admits that "the claims do not require that the claimed polynucleotide have the recited enzymatic activity." Final Action at page 2. Appellant respectfully and additionally points out that claim 1 is directed to "a substantially purified nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5" (Emphasis added). The claims do not require a polynucleotide comprising an ORF or encoding a full length enzyme and thus Appellant need not describe them.

1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Appellant had possession of SEQ ID NO: 5 and its complement and therefore, the claimed invention.

Appellant has provided the nucleotide sequences required by the claims, *e.g.*, SEQ ID NO: 5, as well as, for example, vectors comprising these nucleotide sequences, and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell, and have thus established possession of the claimed invention. *See, e.g.,* specification at page 82, line 18 through page 92, line 8. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences, sequences that have the recited percent sequence identity, or that hybridize under specific conditions to the recited sequences does not mean that Appellant was any less in possession of the claimed nucleic acid molecules.[3] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts."[4] *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir.

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[3] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[4] The Office has asserted that "[a]pplicant cites various pieces of case law which do not refer to polynucleotides, or the particular fact pattern at hand, and are thus non-persuasive." Final Action at page 2. Applicants respectfully submit that it is incorrect as a matter of law to disregard legal precedent simply because the case(s) cited do not concern the biological arts, or more particularly, nucleic acids.

1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NO: 5), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 82, lines 18 through page 92, line 8) and describes how to make the nucleotide sequences and the libraries from which they were originally purified. *See, e.g.,* Example 1 at page 142, *et seq.* Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequences (SEQ ID NO: 5) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[5] for example at page 37, lines 4-8 (describing sequences with labels to facilitate detection), page 50, lines 8-19 (describing fusion nucleic acid molecules), and page 136, line 17 through page 137, line 2 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Moreover, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)).

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[5] It is established patent jurisprudence that Applicant need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

(2) Appellant Has Described the Claimed Invention

The Examiner asserts that because Appellant has not disclosed "any polynucleotides which encode a maize or soybean APRT enzyme," Appellant has allegedly not adequately disclosed the claimed genera of nucleic acid molecules. Final Action at page 3. The Examiner further asserts that "[o]ne of skill in the art would not be able to determine what fragments, and mutants or alleles would fall within the scope of the claims, or even what the unknown residues should be in the full length sequence." *Id.* Moreover, in rejecting Appellant's claims, the Examiner argues that the specification "does not disclose any variants of the non-existent sequence." *Id.* The Examiner appears to assert that each nucleic acid molecule within the claimed genera must be described by its complete structure. Final Action at page 3. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Appellant has satisfied that test for written description.

In particular, Appellant has disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 5. For example, if a particular vector contains the nucleotide sequence of SEQ ID NO: 5, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 5.[6] *See* claim 1. Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention

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[6] If a nucleic acid molecule does not contain SEQ ID NO: 5, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 5 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains a nucleotide sequence having 90% identity to a nucleic acid sequence of SEQ ID NO: 5, then it is a member of that claimed genus of nucleic acid molecules. *See claim 14.*

are readily identifiable - they either contain the nucleic acid sequences of SEQ ID NO: 5 (or its complement), or hybridize under the claimed conditions to SEQ ID NO: 5 (or its complement), or have the requisite percentage sequence identity to SEQ ID NO: 5 (or its complement) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

Thus, claims 1, 12, and 14-19 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

(3) Claim 12 is separately patentable

The Examiner has rejected the claims as allegedly lacking written description because "[t]here is no description of an isolated maize or soybean polynucleotide which is a full length polynucleotide comprising an open reading frame which would encode a full length enzyme." Final Action at page 2-3. However, as has been pointed out, claim 12 is directed to "a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof." *See, e.g.*, specification at page 37, line 16 through page 39, line 23. Even if such a basis for rejection was proper for claims 1 and 18-19, it would not apply to claim 12 which does not recite "a maize or soybean adenine phosphoribosyl transferase or fragment thereof." Applicants have provided an adequate written description for the claimed invention. That is all that is required.

(4) Claims 14-17 are separately patentable

As discussed above, the Examiner has rejected the claims as allegedly lacking written description because "[t]here is no description of an isolated maize or soybean polynucleotide which is a full length polynucleotide comprising an open reading frame which would encode a full length enzyme." Final Action at page 2-3. However, as has been pointed out, claims 14-17 are directed to "a substantially purified nucleic acid

molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 5 or complement thereof." *See, e.g.*, specification at page 37, line 16 through page 39, line 23. Even if such a basis for rejection was proper for claims 1 and 18-19, it would not apply to claims 14-17 which do not recite "a maize or soybean adenine phosphoribosyl transferase or fragment thereof." Applicants have provided an adequate written description for the claimed invention. That is all that is required.

(5) Claims 1, 12 and 18-19 are separately patentable

In rejecting Appellant's claims, the Examiner further argues that the specification "does not disclose any variants of the non-existent sequence." *See* Final Action at page 3. In relying on this, the Examiner argues that "[t]he effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not." *Id.* Even if such a basis for rejection was proper for claims 14-17, it would not apply to claims 1, 12 and 18-19 which do not recite percent sequence identities. Again, Appellant has provided an adequate written description for the claimed invention. That is all that is required.

Thus, claims 1, 12 and 14-19 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

D. The Claimed Nucleic Acids Are Enabled by the Specification

Claims 1, 18 and 19 were erroneously rejected as not being enabled by the specification. The Final Action asserts the claims "contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Final Action pages 3-4. The Examiner apparently maintains that, on the basis of the Wands factors, undue experimentation would be required in order to make and use the claimed invention.

It is well established law that patent applicants are not required to disclose every species enabled by their claims. *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). The enablement requirement is met if the description enables any mode of making and using the invention. The Examiner cites no support for the proposition that the full scope of the claims would require undue experimentation by one of ordinary skill in the art to make or use the claimed invention for the uses described in Appellant's disclosure.

In view of the Examiner's admission that SEQ ID NO: 5 is enabled, and the well established patent jurisprudence that Appellant need not teach "conventional and well-known genetic engineering techniques" (*see, for example, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Appellant submits the Examiner has not met the required burden. Applicants further assert that the use of the transitional phrase "comprising", which leaves the claims "open for the inclusion of unspecified ingredients even in major amounts" (*Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986)) is well-established in patent jurisprudence.

The Final Action attempts to abrogate the Examiner's burden to present evidence that the claims are not enabled by providing generic arguments concerning the alleged unpredictability of nucleic acid hybridization and cloning experiments. Final Action at pages 4-5. In response, Appellant submits that an analysis of the criteria presented by *In re Wands* supports Appellant's position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions and of hybridization parameters, to which a person of ordinary skill in the art has access. *See*, for example, the hybridization parameters set forth in Sambrook *et al.* (eds.), *Molecular Cloning: A Laboratory Manual*, 2d ed., pp. 9.47-11.61, Cold Spring Harbor Laboratory Press, Plainview, New York (1989) and Haymes *et al.*, *Nucleic Acid Hybridization, A Practical Approach*, IRL Press, Washington, D.C. (1985). Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218-219 (C.C.P.A. 1976). Thus, the addition of nucleotides to the recited sequence, the identification of nucleic acid molecules that hybridize to the claimed nucleic acid molecules, and the conception of variations in the claimed nucleic acid molecule that encode a protein having one or more conservative amino acid changes is rendered predictable to one of ordinary skill in the art. Accordingly, it is well-within the ability of one skilled in the art to make or identify the claimed isolated nucleic acid molecules.

The second *Wands* criteria relate to the amount of direction or guidance given. The specification provides guidance, for example, on hybridization parameters in the context of the disclosed utilities and guidance on conservative substitutions in amino acid sequences. Such direction or guidance includes: illustrative hybridization conditions (specification at page 38, line 14 through page 39, line 8); references setting forth methodology that includes the hybridization of nucleic acid molecules to detect polymorphisms (specification at page 45, line 1 through page 47, line 6); references setting forth methodology that includes the hybridization of nucleic acid molecules for *in situ* hybridization (specification at page 73, line 1 through page 74, line 18); and

references setting forth conservative substitutions in amino acid sequences (specification at page 42, lines 3 through page 43, line 21 and Table A). Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The third *Wands* criterion relates to the presence or absence of working examples. The specification provides, for example, isolation of the claimed nucleic acid molecules, evidence of sequence identity, and discusses the use of the claimed SEQ ID NO: 5 in expression systems and the use of the claimed SEQ ID NO: 5 to isolate additional sequences within a genome. *See, e.g.,* specification at page 208, line 10 (Table A) and page 206, line 5 though page 207, line 6 (Example 3); page 124, line 3 through page 127, line 15; page 169, line 9 through page 170, line 2 (Example 1), and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth criterion focuses on the nature of the invention. The present invention relates to nucleic acid molecules, their complements, and nucleic acid molecules that hybridize to the claimed nucleic acid molecules, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 40, line 12 through page 43, line 22 (describing polypeptide molecules and homologues); page 83, line 16 through page 92, line 8 (describing use of the claimed nucleic acid molecules in methods of transforming plants); and page 92, line 9 through page 100, line 18 (construction of expression vectors from the nucleic acid molecules of the present invention).

The fifth and sixth criteria focus on the state of the art and the relative skill in the art. Methods needed to practice the invention are known in the art as well as procedures to carry out the hybridization steps. *See*, for example, Sambrook *et al., Molecular Cloning: A Laboratory Manual,* Cold Spring Harbor (1989), Mailga *et al., Methods in*

Plant Molecular Biology, Cold Spring Harbor (1995) and Birren *et al., Genome Analysis: Analyzing DNA,* 1, Cold Spring Harbor (1997) and Haymes *et al., Nucleic Acid Hybridization, A Practical Approach*, IRL Press, Washington, DC (1985). These references are available to guide use of the claimed nucleic acid molecules. It is clear from these resources, particularly the guidance given on how to carry out the hybridization step, that a person of ordinary skill in the art would be able to use the claimed nucleic acid molecules for the disclosed utilities. Practitioners in this art have available to them considerable knowledge on the conditions and approaches that can be utilized for such a step. As the Examiner has acknowledged, "the skill of those in the art of molecular biology is high." Office Action mailed December 19, 2002 at page 7.

Furthermore, the Examiner's reliance on Moffatt (U.S. Pat. No. 5,770,718) and Moffatt *et al., Gene 143*:211-216 (1994), to establish lack of enablement of the claimed nucleic acid molecules is misplaced. Office Action mailed December 19, 2002 at page 7. Although the Examiner contends the U.S. Patent No. 5,770,718 supports the assertion that the claimed invention is not enabled because "differing known genes are *lacking in sequence similarity*, and that previous hybridization experiments to identify APRT encoding sequences had been unsuccessful" (Office Action at page 7) (emphasis in original), what the patent actually says is that attempts to isolate the apt cDNA in *Arabidopsis* via cross-hybridization with previously isolated apt sequences (*e.g.*, sequences isolated for mouse, hamster and human) were unsuccessful. *See* Col. 2, ll. 50-65, col. 3, l. 52 – col. 4, l. 4. The state of the art must be evaluated based on the filing date of the present application. *See* MPEP § 2164.05(a). Instead, the Examiner's enablement evaluation ignores the sequence disclosed by the Applicants and, as such, it is not proper for the Examiner to conclude based solely on this reference that Applicants' invention would not have been enabled as of its filing date. Thus, contrary to the

examiner's assertion, one skilled in the art could use the nucleic acid molecules of the claimed invention for the disclosed utilities.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative amino acid residue substitutions, identify portions of ARPT encoded by the claimed nucleic acid molecules, use the nucleic acid molecules of the present invention in conjunction with promoter sequences known in the art (*see* specification at page 107, lines 11-24), or use the nucleic acid molecules of the present invention in conjunction with other molecules for the disclosed utilities. Further, the specification discloses sufficient guidance to render the results of substitutions, additions, and deletions within the claimed SEQ ID NOs predictable. *See, e.g.,* specification at page 42, line 3 through page 44, line 21; page 48, line 20 through page 57, line 2; and the sequence listing. Thus, as discussed above, the specification provides sufficient guidance to one of skill in the art to decipher the information necessary to make and use the claimed nucleic acid molecules.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). Here, enablement is satisfied because the art worker is guided by the disclosure to look, for example, to known hybridization parameters and sequence identity in making that determination. As previously stated, performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

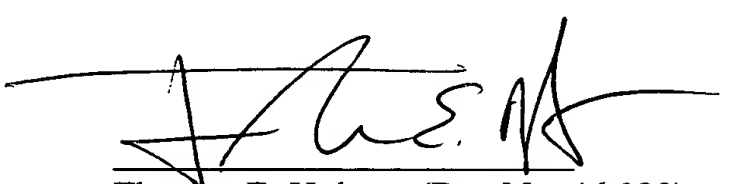
Finally, the Examiner alleges that Appellant "has not provided evidence wherein the inventors or one of skill in the art has obtained a sequence meeting the limitation of claim 1 wherein only the guidance in the specification was used. Such later-produced evidence could be persuasive, as long as it clearly follows the teachings of the specification and does not use techniques, information or procedures which go beyond the teaching in the specification." Final Action at pages 4-5. The Examiner appears to assert that, in order for the claims to be enabled, one of skill in the art must be able to make and use the invention using *only* the guidance in the specification. Such an assertion is incorrect as a matter of law. Appellant need only show that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07, 179 U.S.P.Q. 286, 294 (C.C.P.A. 1973). In order to be enabling, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. *See, e.g.,* M.P.E.P. § 2164.05(a), page 2100-185, *citing In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q. 2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies*, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984).

The Examiner has presented no evidence supporting the allegation that one of ordinary skill in the art would not be able to make or use the claimed nucleic acid molecules in light of Appellant's disclosure. Furthermore, the analysis of the Wands factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, first paragraph, is improper and must be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



Date: May 4, 2004

Thomas E. Holsten (Reg No. 46,098)
Holly L. Prutz (Reg. No. 47,755)
David R. Marsh (Reg. No. 41,408)

ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)
Thomas E. Kelley
(Registration No. 29,938)
Monsanto Company

APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5.

12. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof.

14. A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 5 or complement thereof.

15. The substantially purified nucleic acid molecule of claim 14, wherein said substantially purified nucleic acid molecule has between 95% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

16. The substantially purified nucleic acid molecule of claim 15, wherein said substantially purified nucleic acid molecule has between 98% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

17. The substantially purified nucleic acid molecule of claim 16, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

18. A substantially purified first nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof which specifically hybridizes to a second nucleic acid molecule, the second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof.

19. The substantially purified first nucleic acid molecule according to claim 18 wherein said substantially purified first nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5 or complement thereof.